Office Action Summary	Application No.	Applicant(s)	
	10/587,590	HICKMAN ET AL.	
	Examiner	Art Unit	
	SAMIRA JEAN-LOUIS	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-13,15-18,20 and 25* is/are pending in the application.

4a) Of the above claim(s) *12 and 22-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,13,15-18,20 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/28/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 11-13, 15-18, 20, and 22-25 are currently pending in the application.

Applicant's election of Group I (i.e. method of improving anesthesia recovery) in the reply filed on 11/04/08 is acknowledged. Additionally, given that applicant has amended the claims and narrowed the genus comprising formula I, the species requirement is hereby withdrawn. Moreover, the Examiner respectfully points out that contrary to applicant's statement, the composition entailing a compound of formula I has yet to be examined. Therefore, applicant's statement of an allowable composition is erroneous.

Furthermore, because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Thus, the requirement is deemed proper and is therefore made FINAL.

Claims 12 and 22-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group and species, there being no allowable generic or linking claim. Claims 11, 13, 15-18, 20, and 25 are examined on the merits herein.

Claim Objections

Claims 12 and 22-24 are objected to because of the following informalities: claims are not complete given that the status of the claims reflects them as withdrawn as opposed to cancelled claims which do not require complete listing of the claims. Applicant is required to clearly list the full recitation of the claims along with the claims' status identifiers. Appropriate correction is required.

Provisional Non-Statutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11, 15, and 20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-16 and 27 of copending Application No. 10/587,808 (hereinafter Boettner US Patent Application No. '808). Although the conflicting claims are not completely identical, they are not patentably distinct from each other because both applications are directed to a method of a treatment of a disease for which a NK-1 antagonist is indicated in mammals comprising administering to said mammals a therapeutically effective amount of NK1-antagonists. The claimed invention and co-pending application Boettner '808 are rendered obvious over another as the claimed invention teaches a subgenus of NK-1 antagonists in the treatment of anesthesia recovery whereas Boettner '808 teaches a broad genus of NK-1 antagonists in the treatment of a treatment of a disease for which a NK-1 antagonist is indicated. Thus, the aforementioned claims of the instant

application are substantially overlapping in scope as discussed hereinabove and are prima facie obvious over the cited claims of corresponding application No. 10/587,808.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11, 13, 15, 17-18, 20, and 25 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Plumb (Veterinary Teaching Hospitals St Paul MN. Telazol Data Sheet. 1999, pgs. 1-4) in view of Bronk et al. (WO 03/009848, cited by applicant and filed on an IDS 1449).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Plumb teaches that Telazol is an injectable anesthetic agent chemically related to ketamine (see pg. 1). While its use is indicated for anesthesia wherein its administration lead to rapid effect, adverse effects can also occur (see pgs. 1-2). In particular, Plumb teaches that various adverse effects can occur including emesis, vocalization, erratic and/or prolonged recovery and involuntary muscular twitching (see pg. 2).

Plumb does not specifically teach the use of specific NK-1 antagonists in the method of treating recovery from anesthesia before, during or after general anesthesia. Similarly, Plumb does not teach particular dosages or formulations containing NK-1 antagonists.

Bronk et al. teach the use of NK-1 antagonists to treat abnormal vocalization, hyperactivity and tremors (instant claim 13; see pg. 2, line 36, pg. 3, lines 1-2 and pg. 4, lines 1-6). Preferably, Bronk et al. teach a method directed to treating vocalization and hyperactivity comprising administering to a companion animal in need thereof of a therapeutically effective amount of an NK-1 receptor antagonist (see pg. 4, lines 7-10).

Bronk et al. further teach that such therapeutic composition can be administered to companion animals such as dogs, cats, and horses (instant claim 25; see pg. 4, lines 21-22). Particular NK-1 receptor antagonists include (2S, 3S)-N-(5-tert-butyl-2-methoxyphenyl)-2-diphenylmethyl-1-azabicyclo[2,2,2]octan-3-amine, (2S, 3S) (2-benzhydryl-1-aza-bicyclo[2,2,2]oct-3-yl) (5-tert-butyl-2-methoxy-benzyl)-amine, and salts thereof (instant claims 11 and 15; see pg. 7, lines 25-26, pg. 9, line 27, and pg. 11, lines 1-5). The NK-1 antagonists can be administered orally or parenterally in dosages ranging from about 0.01 mg to about 5 mg/kg of body weight (instant claims 17-18 and 20; see pg. 12, lines 10-18 and pg. 13, lines 29-30). However, Bronk et al. teach that dosage variations may occur depending upon the species of animal being treated and its individual response to said medicament, as well as the type of pharmaceutical formulation, the time period and interval at which such administration is carried out (see pg. 12, lines 32-34).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to administer the composition of Bronk et al. after general anesthesia since Plumb teach that adverse effects such as vocalization or muscle twitching occur after administration of anesthetic agents and given that Bronk et al. teach the compositions as effective for vocalization and tremors. Thus, given the teachings of Plumb and Bronk, one of ordinary skill would have been motivated to utilize the composition of Bronk et al. for treating recovery from anesthesia in light of the disclosure of Bronk and Plumb with the reasonable expectation of providing a method

that shows improvement in recovery from anesthesia and a method effective in treating vocalization and tremors.

Claim 16 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Plumb (Veterinary Teaching Hospitals St Paul MN. Telazol Data Sheet. 1999, pgs. 1-4) in view of Bronk et al. (WO 03/009848, cited by applicant and filed on an IDS 1449) as applied to 11, 13, 15, 17-18, 20, and 25 and in further view of Quallich et al. (6,255,320 B1, cited by applicant and filed on an IDS 1449).

The Plumb and Bronk references are as discussed above and incorporated by reference herein.

However, Plumb and Bronk do not teach the citrate salt of the compound of formula I.

Quallich et al. teach a crystalline polymorphic form (2S,3S)-N-(methoxy-5-t-butylphenylmethyl)-2-diphenylmethyl-1-azobicyclo[2,2,2,]octan-3-amine citrate and pharmaceutical compositions containing such compounds as stable and compositions that can be used intravenously (i.e. parenterally; instant claim 16; see abstract and col. 1, lines 45-50). Additionally, Quallich et al. teach that such compounds have NK-1 receptor antagonist activity, can comprise a pharmaceutical carrier and administered in preferred dosage ranges of 40-200 mgA/day (see col. 1, lines 66-67 and col. 2, lines 1-2).

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to administer the composition of Quallich et al. after general anesthesia since Plumb treats adverse effects such as vocalization or muscle twitching occurring after administration of anesthetic agents, and given that Bronk et al. teach the use of compositions containing NK-1 receptor antagonists as effective for vocalization and tremors, and given that Quallich et al. teach that the citrate salt form is known for its stability. Thus, given the teachings of Plumb, Bronk and Quallich, one of ordinary skill would have been motivated to utilize the citrate salt form of formula I into the composition of Bronk et al. as taught by Quallich et al. for treating recovery from anesthesia in light of the disclosure of Plumb with the reasonable expectation of providing a method that shows improvement in recovery from anesthesia and a method effective in treating vocalization and tremors using stable compositions.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1617

01/08/2008

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617